

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEC 14 1995

Dr. Sally Van Wert, Ph.D.  
Manager, Regulatory Affairs-Biotechnology  
AgrEvo USA Company  
Little Falls Center One  
2711 Centerville Road  
Wilmington, DE 19808

Dear Dr. Van Wert:

This is in regard to AgrEvo's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on genetically modified corn, specifically transformation events T14 and T25. According to AgrEvo, transformation events T14 and T25 are modified to express a synthetic version of the pat gene, similar to the pat gene isolated from *Streptomyces viridochromogenes*. The pat gene encodes the phosphinothricin acetyltransferase (PAT) protein, which reportedly confers tolerance to the herbicide glufosinate ammonium.

In August 1994, AgrEvo met with FDA to discuss their proposed safety and nutritional assessment of corn containing transformation events T14 and T25. As part of bringing AgrEvo's consultation regarding these products to closure, AgrEvo submitted a summary assessment of corn containing transformation events T14 and T25 on August 29, 1995, and an amendment dated October 28, 1995.

These communications informed FDA of the steps taken by AgrEvo to ensure that these products comply with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that AgrEvo has concluded that corn grain (kernels), fodder, and silage derived from the new varieties, are not materially different in composition, safety, and other relevant parameters from corn grain, fodder, and silage currently on the market and that the genetically modified corn does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0029. This file will be maintained in the Office of Premarket Approval.

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Based on the information AgrEvo has presented, we have no further questions concerning grain, fodder, and silage from events T14 and T25 corn at this time. However, as you are aware, it is AgrEvo's continued responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely,

/s/

Alan M. Rulis, Ph.D.  
Director  
Office of Premarket Approval  
Center for Food Safety and  
Applied Nutrition

cc: HFS-200 HFS-205 HFS-226 HFS-235 HFS-246 HFS-247  
HFS-13 HFS-144 HFV-200 HFV-221 HFV-226 BNF0029  
HFS-206